



HSIA

halogenated
solvents
industry
alliance, inc.

November 30, 2011

Dr. Ruth Lunn
Director
Office of the Report on Carcinogens
DNTP, NIEHS, PO Box 12233, MD K2-14
Research Triangle Park, North Carolina 27709

Re: Proposed Review Process for 13th Report on Carcinogens

Dear Dr. Lunn:

The Halogenated Solvents Industry Alliance (HSIA) offers these comments on the proposed process for development, review, and issuance of the 13th Report on Carcinogens (RoC) recently released by the National Toxicology Program (NTP). 76 Fed. Reg. 67200 (October 31, 2011).

Unaccountably, comments were requested within thirty days, even though the previous RoC (the 12th) has proven to be very controversial and changes in the process are clearly of great interest to a wide range of parties. A number of parties requested an extension of this deadline, but those requests have been denied. The denial we received states: "While we appreciate suggestions, we believe that the announced public comment period process and timeline provide a reasonable opportunity for interested parties to provide external input..." and "We will move forward with soliciting public comment, finalizing the process, and presenting the process changes to our Board of Scientific Counselors at their next scheduled meeting on December 15, 2011." We question how it will be possible for NTP to take into account the comments received, and make any meaningful changes to the proposed process, in time to present anything to the Board of Scientific Counselors (BSC) in two weeks except the process as it has been proposed.

The issue of greatest concern to HSIA, which has participated in previous RoC listing decisions, is the continued downgrading of the role of the NTP Board of Scientific Counselors. At a time when NTP's listing decisions are attracting criticism from the scientific community and enhanced public scrutiny, this seems to be movement in the wrong direction. In the 10th Report on Carcinogens, the BSC played a critical role, in some cases disagreeing with the recommendations presented by NTP staff. For the 12th RoC, the BSC review had been moved forward to the draft profile stage. There follows NTP's response to comment submitted during that rulemaking that the BSC should review the listing decision as well:

“Peer Review of Draft Substances Profiles

- NTP should invite the NTP Board of Scientific Counselors (BSC) to comment on the NTP 's listing decision as well as its scientific justification for listing.

“NTP Response: Historically, NTP asked a subcommittee of the BSC for its opinion on the listing status of candidate substances; the expert panels will now have this role. The RoC review process defines a new role for the BSC. The BSC's charge will be to determine whether the scientific information cited in the draft substance profile for a candidate substance is technically correct, clearly stated, and supports the NTP's policy decision regarding its listing status in the RoC. The NTP will not ask the BSC to comment on its policy decision regarding listing status of the candidate substance.”

The BSC is chartered to advise the NTP “Executive Committee and Program Director on matters of scientific program content, to evaluate the scientific merits of the intramural and collaborative programs of the NTP, and to provide external scientific advice on NTP activities.” It should not be tasked with providing glorified literature reviews to support the listing objectives of NTP staff.

NTP’s response to public comments in connection with the 12th RoC justifying the downgrading of the BSC characterizes the listing decision as one of policy as opposed to science. We question whether the decision as to whether to list a compound as known or reasonably anticipated to be a human carcinogen is best defined as policy, as opposed to science, defined as “the systematic pursuit of knowledge,” in the case of the natural sciences “knowledge concerned with the physical world and its phenomena.” In any event, it would appear that the process proposed for the 13th Report continues the 12th Report policy of limiting the BSC's role, but with the additional qualification that the external advisory group that peer reviews the draft RoC Monograph (presumably the equivalent of the draft substance profile) now may be either the BSC or an "expert panel" apparently convened by the Office of the Report on Carcinogens. We have not seen criteria to guide selection of the expert panel. However it is chosen, limiting the review to whether the draft profile is technically correct and clearly stated seems intended to avoid any meaningful peer review whatsoever.

Enclosed is an excerpt of NTP’s own summary of the procedure it followed in 2000 in compiling the 10th RoC. *See* 66 Fed. Reg. 13334 (March 5, 2001). The earlier process included, in addition to the RG1 (NTP internal review) and RG2 (interagency review), an external peer review by the BSC Report on Carcinogens Subcommittee, all in the context of the listing decision. We submit that such an external peer review of the listing decision is the very minimum process check that NTP could adopt that will comply with the Information Quality Act Guidelines applicable to influential scientific information. These include: (i) the obligation to state clearly how analytic results are generated by making transparent the

specific data used, various assumptions, specific analytic methods, statistical procedures, and sources of error, (ii) the requirement that scientific conclusions be based on best available science and supporting studies, particularly peer-reviewed studies, conducted in accordance with sound and objective scientific practices, and (iii) a commitment to rigorous peer review designed to obtain input from qualified reviewers for accuracy, completeness, and quality. See NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public, § 7.¹

Peer review of RoC listing decisions by the NTP Board of Scientific Counselors was historically the only outside check for accuracy, completeness, and quality on the proposed NTP staff listing decision. Indeed, the NIH Guidelines expressly address (in § V(2)(d)) the BSC's peer review function for the RoCs: "External peer review of the nominations is performed by a subcommittee of the NTP Board of Scientific Counselors in open, public meetings."

HSIA strongly urges that a review process be adopted that reaffirms, rather than diminishes, the important role played by the NTP Board of Scientific Counselors. Thank you for the opportunity to comment.

Very truly yours,

[Redacted]

Faye Graul
Executive Director

Enclosure

cc: NTP Board of Scientific Counselors
Cass R. Sunstein, Esq.

¹ <http://aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml>.

SUMMARY OF RG1,[1] RG2[2] AND NTP BOARD SUBCOMMITTEE[3]
RECOMMENDATIONS FOR THE AGENTS, SUBSTANCES, MIXTURES OR
EXPOSURE CIRCUMSTANCES REVIEWED IN 2000 FOR LISTING IN, DELISTING
FROM, OR UPGRADING IN THE REPORT ON CARCINOGENS,[4] 10TH EDITION

Nominations/CAS No.	Primary uses or exposures	RG1 action	RG2 action	NTP board subcommittee action
Broad Spectrum UV Radiation (UVR) and UVA, and UVB, and UVC. * *	Solar and artificial sources of ultraviolet radiation. * *	Motion to list UVR as known to be a human carcinogen passed by unanimous vote (6/0). * *	Motion to list UVR as known to be a human carcinogen passed by unanimous vote (8/0). * *	Motion to list UVR as known to be a human carcinogen passed by unanimous vote (10/0). * *

[1] The NIEHS Review Committee for the Report on Carcinogens (RG1).

[2] The NTP Executive Committee (Agencies from the NTP Executive Committee represented on RG2 include: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), National Center for Environmental Health of the Centers for Disease Control and Prevention (NCEH/CDC), National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA), National Institute for Occupational Safety and Health/CDC (NIOSH/CDC), Occupational Safety and Health Administration (OSHA), National Cancer Institute of the National Institutes of Health (NCI/NIH), and National Institute of Environmental Health Sciences/NIH(NIEHS/NIH) Interagency Working Group for the Report on Carcinogens (RG2).

[3] The NTP Board of Scientific Counselors Report on Carcinogens Subcommittee (the External Peer Review Group).

[4] RoC-Report on Carcinogens.

Source: 66 Fed. Reg. 13334-13337 (March 5, 2001)